

### **Remarks**

Claims 1 and 8-12 are pending in the application. Claims 1, 9, and 12 have been amended. Support for the claim amendments can be found throughout the application, including the claims as originally filed. Importantly, no new matter has been added to the claims. The amendment to the claims should not be construed to be an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicant reserves the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

### **Response to Rejections under 35 U.S.C. § 112¶2**

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 112¶2 based on the Examiner's contention that they are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner contends that the phrase 'radionuclide being associated with a targeting moiety' renders the claims indefinite because it is not clear how the radionuclide is associated with the targeting moiety. The Applicants respectfully traverse this rejection.

Independent claims 1, 9, and 12, as amended, state that the radionuclide is chemically bonded to the targeting moiety. Support for this amendment can be found on page 7, lines 11-14, of the specification. The Applicants respectfully submit that one of ordinary skill in the art would know the metes and bounds of the claims as amended.

Accordingly, the Applicants respectfully request the withdrawal of the rejections based on 35 U.S.C. § 112¶2.

### **Response to Rejections under 35 U.S.C. § 103(a)**

Claims 1 and 8-12 stand rejected under 35 U.S.C. § 103(a) based on the Examiner's contention that they are obvious over Calenoff (U.S. Patent No. 6,025,477) in view of Conti et al. (U.S. Patent No. 6,331,287) and further in view of Fritzberg et al. (U.S. Patent No. 5,175,343). The Examiner contends that it would have been obvious to

one of ordinary skill in the art at the time the invention was made to prepare a cardiovascular imaging agent comprising a radionuclide associated with a targeting moiety wherein the targeting moiety is selected from the 7 possible types of targeting moieties expressed in independent claims 1, 9 and 12. The Applicants respectfully traverse this rejection.

First, the Applicants wish to thank the Examiner for discussing the final office action with the Applicants' agent in a phone call on February 9, 2005, in which she acknowledged that her contention that the claims encompassed antibodies as targeting moieties was incorrect. Therefore, the following arguments are reproduced from our Response dated July 22, 2004, and reiterate why Calenoff in view of Conti et al. and further in view of Fritzberg et al. do not render the claims obvious.

Calenoff discloses antigens the presence of which are indicative of atherosclerotic plaque. Calenoff discloses radioimaging atherosclerotic plaque using an antibody which specifically binds to an atherosclerotic plaque specific antigen. Therefore, in Calenoff, the targeting moiety is an antibody. See column 2, lines 48-53, column 3, lines 18-21 and lines 65-66, and column 8, lines 11-17. Examples of antibodies include those listed in column 7 of Calenoff.

Independent claims 1, 9, and 12 list the possible targeting moieties as (i) cells, including muscle cells, macrophages, foam cells, monocytes, polymorphonuclear cells, cellular fragments and analogs thereof, (ii) colony stimulating factors, and platelet factor 4, (iii) growth factors, (iv) cytokines, interferons, and tumor necrosis factors, (v) cellular sources of energy for metabolic active plaque formation, (vi) lipids and lipid receptors, and (vii) component of clotting cascades. This list does not include antibodies. Antibodies are plasma proteins that bind specifically to antigens. The 7 categories of targeting moieties listed above do not bind to antigens. Given that it is known in the art that antibodies bind specifically to antigens, it would not be obvious from Calenoff to use other types of targeting moieties because there would be no expectation of success. This is especially true for the targeting moieties listed in independent claims 1, 9, and 12 which are not known to bind antigens.

Conti et al. was cited by the Examiner only for its teachings that  $^{18}\text{F}$  is a label for PET imaging. Therefore, Conti et al. does not make up for Calenoff's deficiency of not teaching the targeting moieties of independent claims 1, 9, and 12.

Fritzberg et al. was cited by the Examiner for its teaching of the importance of generating a kit. Therefore, Fritzberg et al. also does not make up for Calenoff's deficiency of not teaching the targeting moieties of independent claims 1, 9, and 12.

Because it would not be obvious to prepare a cardiovascular imaging agent where the targeting moiety is selected from the list contained in independent claims 1, 9, and 12 in view of the cited references, either individually or in combination, the Applicants respectfully submit that the inventions as claimed are novel and non-obvious over the prior art.

Accordingly, the Applicants respectfully request the withdrawal of the rejections based on 35 U.S.C. § 103(a).

#### **Request for the Withdrawal of Final Status**

The Applicants respectfully request that the Examiner enter the present Amendment and Response and examine the amended claims rather than issue an Advisory Action based on the fact that had the Examiner not mistakenly believed that the claims encompassed antibodies as targeting moieties, she would have fully examined the claims in our Response dated July 22, 2004 when the Applicants were entitled to full examination rather than issue a final office action.

Therefore, the Applicants respectfully request the withdrawal of final status of the outstanding office action.

#### **Fees**

The Applicants believe they have provided for the required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any additional required fee to our Deposit Account, 06-1448.

**Conclusion**

For the foregoing reasons, the Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the pending claims are now in condition for allowance and early notification to this effect is earnestly solicited. If any questions are raised by this Amendment and Response, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
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